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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

GENERAL ATOMICS, DIAZYME
LABORATORIES DIVISION,

No. C 05-04074 SI

Plaintiff,

CLAIM CONSTRUCTION ORDER

v.

AXIS-SHIELD ASA,

Defendant.

On September 13, 2006, the Court held a claim construction hearing in this case. Having considered the arguments of counsel and the papers submitted, the Court rules as follows.

BACKGROUND

Plaintiff General Atomics is a California corporation that sells enzymic homocysteine assays that detect the level of homocysteine in human samples.¹ On October 11, 2005, General Atomics filed this action against Axis-Shield ASA, a Norwegian corporation, seeking a declaratory judgment that its assays did not infringe U.S. Patents owned by Axis Shield. Although the complaint originally sought a declaration of non-infringement as to four Axis-Shield patents, only two remain in this suit: U.S. Patent No. 5,631,127 (“Patent ‘127”); and U.S. Patent No. 5,958,717 (“Patent ‘717”).

On July 19, 2006, the Court granted plaintiff General Atomics’ motion for summary judgment of non-infringement. After granting summary judgment, however, the Court allowed defendant Axis-

¹Homocysteine is a naturally occurring amino acid found in the human body. Elevated levels of homocysteine can signify various disorders, including cardiovascular disease. *See* Patent ‘127, 1:8-49.

1 Shield to amend its preliminary infringement contentions.

2 Axis-Shield contends that General Atomics' assay infringes both Patent '127 and Patent '717.
3 These patents describe methods for detecting levels of homocysteine in samples of blood, plasma, or
4 urine, as well as kits for performing those methods. The patents both stem from the same priority
5 application, and have substantially identical specifications.²

6

7 **LEGAL STANDARD**

8 Claim construction is a matter of law. *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 372
9 (1996). Terms contained in claims are "generally given their ordinary and customary meaning."
10 *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). "[T]he ordinary and customary meaning
11 of a claim term is the meaning that the term would have to a person of ordinary skill in the art in
12 question at the time of the invention." *Id.* In determining the proper construction of a claim, a court
13 begins with the intrinsic evidence of record, consisting of the claim language, the patent specification,
14 and, if in evidence, the prosecution history. *Id* at 1313. "The appropriate starting point . . . is always
15 with the language of the asserted claim itself." *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d
16 1182, 1186 (Fed. Cir. 1998). "[T]he language of the claim frames and ultimately resolves all issues of
17 claim interpretation." *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023 (Fed. Cir. 1997). In the
18 absence of an express intent to impart a novel meaning to claim terms, an inventor's claim terms take
19 on their ordinary meaning. However, claims are always read in view of the written description. *See*
20 *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

21 The written description can provide guidance as to the meaning of the claims, thereby dictating
22 the manner in which the claims are to be construed, even if the guidance is not provided in explicit
23 definitional format. *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d
24 1337, 1344 (Fed. Cir. 2001). In other words, the specification may define claim terms "by implication"

25
26 ²Both claims at issue are written in "Jepson" format, in which the independent claims contain
27 three parts: "(1) a preamble comprising a general description of all the elements or steps of the claimed
28 combination which are conventional or known, (2) a phrase such as 'wherein the improvement
comprises,' and (3) those elements, steps and/or relationships which constitute that portion of the
claimed combination which the applicant considers as the new or improved portion." 37 C.F.R. §
1.75(e); *see also Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997).

such that the meaning may be “found in or ascertained by a reading of the patent documents.” *Vitronics*, 90 F.3d at 1584 n.6. Although claims are interpreted in light of the specification, this “does not mean that everything expressed in the specification must be read into all the claims.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed. Cir. 1983). For instance, limitations from a preferred embodiment described in the specification generally should not be read into the claim language. *See Comark*, 156 F.3d at 1187. However, it is a fundamental rule that “claims must be construed so as to be consistent with the specification.” *Phillips*, 415 F.3d at 1316. Therefore, if the specification reveals an intentional disclaimer or disavowal of claim scope, the claims must be read consistent with that limitation. *Id.*

9 Although not as persuasive as intrinsic evidence, a court may also rely on extrinsic evidence,
10 which “consists of all evidence external to the patent and prosecution history, including expert and
11 inventor testimony, dictionaries, and learned treatises,” to determine the meaning of claim language.
12 *Phillips*, 415 F.3d at 1317. All such extrinsic evidence should be evaluated in light of the intrinsic
13 evidence. *Id.* at 1319.

DISCUSSION

I. Claim term constructions to which the parties agree

17 In addition to the agreed constructions listed in Exhibit A to the Joint Claim Construction and
18 Prehearing Statement (Docket No. 70), the parties have further agreed to the following constructions.

A. “second enzyme” (claim 2 of Patents ‘127 and ‘717)

20 The proper construction of “second enzyme” is “an enzyme other than the homocysteine
21 converting enzyme.”

B. "sample" (claims 1 and 18 of Patent '127; claim 11 of Patent '717)

23 The proper construction of “sample” is “any substance or a mixture thereof that is assayed for
24 homocysteine.”

C. “inactive SAH-Hydrolase” (claim 23 of Patent ‘127; claim 12 of Patent ‘717)

26 The proper construction of “inactive SAH-hydrolase” is “SAH-hydrolase that is incapable of
27 acting as a catalyst”

D. "in a second compartment a reducing agent, whereby to produce on admixture of

**the contents of said first and second compartments activated SAH-hydrolase”
(claim 23 of Patent ‘127; claim 12 of Patent ‘717)**

The proper construction of “in a second compartment a reducing agent, whereby to produce on admixture of the contents of said first and second compartments activated SAH-hydrolase” is “the contents of the second compartment of the kit includes a reducing agent, and when the contents of the first and second compartments are mixed, activated SAH-hydrolase is produced”

E. “without chromatographic separation assessing a non-labelled analyte” (claim 1 of Patents ‘127 and ‘717)

9 The proper construction of “without chromatographic separation assessing a non-labelled
10 analyte” is “assessing a non-labelled analyte using a technique that does not include chromatographic
11 separation.”

F. “assessing an analyte” (claim 1 of Patents ‘127 and ‘717)

14 The proper construction of “assessing an analyte” is “quantitative or qualitative determination
15 in the sense of obtaining an absolute value for the amount or concentration of the analyte present in the
16 sample or obtaining an index, ration, percentage, visual or other value indicative of the level of analyte
17 in the sample. The chemical species actually detected need not be the analyte itself but may for example
18 be a derivative thereof or some further substance.”

II. Disputed terms in claim 1 of Patents '127 and '717

Claim 1 of Patent '127 reads as follows:

In a method for assaying homocysteine in a sample, said method comprising the steps of (i) contacting said sample with a homocysteine converting enzyme and at least one substrate for said enzyme other than homocysteine, and (ii) assessing an analyte which is a substrate for said enzyme, wherein the improvement comprises in step (i) contacting said sample with said substrate other than homocysteine and in step (ii) without chromatographic separation assessing a non-labelled analyte selected from the group consisting of a homocysteine co-substrate and the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme.

Patent '127, 22:44-55. Claim 1 of Patent '717 is similar, and provides:

In a method for assaying homocysteine in a sample, said method comprising the steps of (i) contacting said sample with a homocysteine-converting enzyme and (ii) assessing

1 an analyte, wherein the improvement comprises in step (ii) without chromatographic
2 separation assessing a non-labelled analyte selected from the group consisting of the
3 homocysteine conversion products of the enzymic conversion of homocysteine by said
4 enzyme.

5 Patent '717, 22:60-67. The parties dispute the following terms of claim 1.

6 **A. "homocysteine converting enzyme"**

7 Axis-Shield seeks a broad construction of this term: an "enzyme that catalyzes a reaction
8 between homocysteine and a co-substrate (if any) that is not homocysteine to produce one or more
9 products that do not include homocysteine." Axis-Shield's construction would thus include any enzyme
10 that could potentially catalyze a reaction involving homocysteine, even if the enzyme does not in fact
11 act on homocysteine in the assay at issue. General Atomics' proposed construction is much more
12 narrow: "an enzyme that acts on the sample homocysteine being assayed." General Atomics'
13 construction would thus include only enzymes that act on the homocysteine existing in the original
14 sample, and not enzymes that act only on homocysteine produced at some other point in the assay.

15 A natural reading of claim 1, at first blush, favors General Atomics' proposed construction. If
16 the assay method is to result in "the homocysteine conversion products of the enzymic conversion of
17 homocysteine by said enzyme," then the enzyme must convert the homocysteine in the sample. Axis-
18 Shield argues that this logic, however, ignores the ability of the claimed assay to run "in reverse."

19 The "forward" reaction is as follows: The sample containing homocysteine is contacted with
20 a co-substrate, adenosine, and an enzyme, SAH-hydrolase. The SAH-hydrolase catalyzes a reaction
21 between the homocysteine and the adenosine, forming SAH. The amount of SAH or remaining
22 adenosine is then measured, by which the amount of homocysteine in the original sample can be
23 determined. *See* Patent '127, 3:40-47.

24 The reverse or "inhibition" (or "hydrolytic") embodiment of claim 1 functions differently. *See*
25 Patent '127, 3:16-33, 3:48-55. The sample containing homocysteine is contacted with SAH and SAH-
26 hydrolase. Some of the SAH-hydrolase acts to break apart SAH into its component parts, adenosine and
27 homocysteine. Other SAH-hydrolase molecules, however, bind to the homocysteine in the sample, and
28 are unavailable to break up the SAH. Therefore, if the assay begins, for example, with equal parts SAH
and SAH-hydrolase, not all of the SAH will be broken up, as some of the SAH-hydrolase will be

1 occupied with the homocysteine. The amount of adenosine is then measured, and compared to the
2 amount of adenosine that would be found if all of the SAH-hydrolase had been engaged to break up
3 SAH. The difference will be proportionate to the amount of homocysteine in the sample. In this
4 “reverse” reaction, the homocysteine converting enzyme, SAH-hydrolase, does not actually convert any
5 of the homocysteine in the sample. Axis therefore argues that General Atomics’ proposed construction
6 is too narrow, as it would preclude this embodiment.

7 This “reverse” embodiment, however, standing alone, is inconsistent with claim 1. The natural
8 reading of the last step of claim 1, “without chromatographic separation assessing a non-labelled analyte
9 selected from the group consisting of a homocysteine co-substrate and the homocysteine conversion
10 products of the enzymic conversion of homocysteine by said enzyme,” is that homocysteine is, at some
11 point, converted into other products by the enzyme. *See Order Granting Summ. J. 9-14* (Docket No. 83).
12 In the “reverse” reaction described above, homocysteine is never converted; some is bound to the SAH-
13 hydrolase, but absent a co-substrate, SAH-hydrolase effects no change on the homocysteine.

14 At oral argument, Axis-Shield asserted that the reverse reaction does not occur in isolation, but
15 rather is part of simultaneous forward and reverse reactions, and in that context, the assay is consistent
16 with claim 1, because SAH serves as both a substrate and a homocysteine conversion product. The
17 simultaneous, forward and reverse, “inhibition” embodiment functions as follows. As in the pure
18 “reverse” reaction, the homocysteine sample, SAH, and SAH-hydrolase, are placed together. Some of
19 the SAH-hydrolase breaks up the SAH, and some bonds to the homocysteine. As the SAH is broken
20 into homocysteine and adenosine, the newly-freed adenosine can bond with the SAH-hydrolase, to
21 which homocysteine is already bound, thereby forming new SAH particles (this is the “forward”
22 reaction). As this process continues, the rate of adenosine formation will change. The rate of change
23 in adenosine formation will be proportionate to the amount of homocysteine in the sample. In this
24 “inhibition” embodiment, SAH is both a substrate, because SAH-hydrolase acts on it, and is a
25 homocysteine conversion product, because the freed adenosine combines with homocysteine to create
26 new SAH.

27 This “inhibition” reaction is clearly described in the patent as a possible embodiment of the
28 claims. *See* patent ‘127 at 3:16-38, 3:48-55. The Court also finds that this embodiment does not

1 conflict with claim 1, as SAH acts as both a substrate and a homocysteine conversion product.
2 However, this finding does not compel the Court to agree with Axis-Shield's broad construction of
3 "homocysteine converting enzyme." Axis-Shield argues that General Atomics' construction, which is
4 the natural construction, is too narrow because in the reverse reaction the enzyme does not actually act
5 on the sample homocysteine. However, as discussed, the reverse reaction alone is inconsistent with
6 claim 1. Only in the context of a continuous forward-reverse, "inhibition" embodiment, is the reverse
7 reaction consistent with claim 1. In this context, the enzyme *does* catalyze the homocysteine in the
8 sample. As adenosine is freed, it combines with homocysteine, using the SAH-hydrolase enzyme,
9 forming new SAH. The freed adenosine makes no distinction between the homocysteine which is in
10 the sample to begin with, and the homocysteine freed from SAH. The "homocysteine converting
11 enzyme" in the inhibition embodiment thus does in fact convert homocysteine from the sample. There
12 is therefore nothing to prevent the Court from adopting the natural reading of "homocysteine converting
13 enzyme," which is "an enzyme that acts on the sample homocysteine being assayed." This construction
14 encompasses both the "forward" and "inhibition" embodiments of the assay, without being over-broad.
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16 **B. "contacting said sample with a homocysteine converting enzyme and at least one
17 substrate for said enzyme other than homocysteine"**

18 Axis-Shield's proposed construction is "any joining of said sample with a homocysteine
19 converting enzyme [and at least one substrate for said enzyme other than homocysteine]." General
20 Atomics' construction is "adding from an external source a homocysteine converting enzyme and a
21 substrate for the enzyme other than homocysteine to the sample prior to the conversion of
22 homocysteine." Thus the principal contentions are "any joining" versus "adding from an external
23 source," and General Atomics' specification that the contact occur "prior to the conversion of
24 homocysteine."

25 **1. "Any joining" versus "adding from an external source"**

26 Axis-Shield argues that "adding from an external source" is too narrow, and would preclude one
27 of the contacting techniques disclosed in the patents. Because the preferred enzyme, SAH-hydrolase,
28 tends to become inactive during storage, the patents describe a method by which inactive SAH-

1 hydrolase, already combined with the sample, can be activated by a reducing reagent, in this example
2 DTT. *See* Patent '127, 7:42-67. An ordinary reading of "contacting" is broad enough to include a
3 method such as this, where the contact occurs through the addition of an activating agent, albeit from
4 an external source. "Contacting" does not require, as General Atomics' construction suggests, that the
5 enzyme be added, in active form, from an external source.

6 **2. "prior to the conversion of homocysteine"**

7 If the homocysteine converting enzyme is to convert the homocysteine in the sample being
8 assayed, as discussed *supra*, then naturally the contact between the sample and the enzyme must occur
9 prior to the conversion of the homocysteine by the enzyme. Moreover, this construction is consistent
10 with the fact that "contacting" is "step (i)" of the claimed method.

11 Accordingly, the Court construes "contacting said sample with a homocysteine converting
12 enzyme and at least one substrate for said enzyme other than homocysteine," as "joining the sample with
13 a homocysteine converting enzyme and a substrate for the enzyme other than homocysteine prior to the
14 conversion of homocysteine by said enzyme." "Joining" includes the activation of an inactive
15 homocysteine converting enzyme already present with the sample.

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17 **C. "chromatographic separation"**

18 The principal conflict between the parties here is whether the second phase involved in
19 chromatographic separation should be described as "moving" or "mobile." Axis-Shield has provided
20 convincing evidence that chromatographic separation involves one stationary phase, through or past
21 which another phase moves. *See* Axis-Shield's Opening Br. 12-16 (citing Ravindrarath, *Principles and*
22 *Practice of Chromatography* 45 (Ellis Horwood Limited 1989)). Whether a particular method, such as
23 plaintiff's "batch chromatography," involves a "moving" phase is an infringement question that the
24 Court need not decide at this stage. Accordingly, the Court construes "chromatographic separation" as
25 "a method for separation of the components of a sample, in which the components are distributed
26 between two phases, one of which is stationary while the other moves."

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28 **D. "assaying homocysteine in a sample"**

1 General Atomics' proposed construction of "assaying homocysteine in a sample" is "the entire
2 process of determining the relative amount of homocysteine in a mixture, including but not limited to
3 the contacting and assessing steps of the claim." Axis-Shield convincingly argues that "the entire
4 process" is unnecessary, and potentially confusing. Similarly, "including but not limited to the
5 contacting and assessing steps of the claim," while not incorrect, appears superfluous. Accordingly, the
6 Court construes "assaying homocysteine in a sample" to mean "determining the amount or concentration
7 of homocysteine in a sample."

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9 **III. Disputed terms in claim 2 of Patents '127 and '717: "a product of enzymic conversion of
10 said analyte by said second enzyme"**

11 Claim 2 of both patents reads: "The method as claimed in claim 1 wherein said sample is
12 contacted with a second enzyme serving to convert said analyte and assessment of said analyte is
13 effected indirectly by assessment either of a substrate of said second enzyme other than said analyte or
14 of *a product of enzymic conversion of said analyte by said second enzyme.*" (emphasis added).

15 General Atomics argues that construction of this term is unnecessary because "the Court has
16 determined the meaning of 'homocysteine conversion products.'" Responsive Br. 24-25. General
17 Atomics' logic is unclear. The "product" at issue in this claim results from the conversion of the
18 analyte, not from conversion of homocysteine. Neither party has ever alleged that homocysteine is an
19 analyte. The Court's construction of "homocysteine conversion products" is therefore irrelevant to
20 construction of this phrase, which is easily accomplished using the plain text of the claim. The proper
21 construction of "a product of enzymic conversion of said analyte by said second enzyme" is "a product
22 of the reaction in which the said analyte is a substrate of the second enzyme."

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24 **IV. Disputed terms in claims 8 and 9 of Patent '127: "said analyte"**

25 Claims eight and nine of Patent '127 state: "8. The method as claimed in claim 1 wherein *said
26 analyte* is a said conversion product. 9. The method as claimed in claim 8 wherein *said enzyme* is
27 [SAH-hydrolase] and *said analyte* is [SAH]." (emphasis added).

28 Construction of this term requires resolution of the Jepson issue discussed at length in the

1 Court's Order Granting Summary Judgment of Non-infringement. *See* Order 5-8 (Docket No. 83).
2 Specifically, construction of "said analyte" requires the Court to determine whether the analyte must
3 be a "substrate for [the homocysteine converting] enzyme," as stated in the preamble of claim 1. Axis-
4 Shield suggests that "[s]ince the only current infringement contentions relate to SAH-hydrolase, it is not
5 clear that the Court needs to resolve this issue." However, claim construction requires that the Court
6 define disputed terms, and "said analyte" is clearly a disputed term.

7 To review, the Jepson issue arises because of an apparent conflict between the definition of
8 "analyte" in the preamble of claim 1, and its definition in the description of improvements, later in claim
9 1. The preamble to claim 1 of Patent '127 describes the second step of the invention as "assessing an
10 analyte which is a substrate for said enzyme." The "improvement" half of claim 1 describes the second
11 step of the invention as "assessing a non-labelled analyte selected from the group consisting of a
12 homocysteine co-substrate and the homocysteine conversion products of the enzymic conversion of
13 homocysteine by said enzyme." Taking the preamble and improvements together, the analyte must be
14 (1) a substrate for the enzyme; (2) non-labelled; and either (3) a homocysteine co-substrate or (4) "the
15 homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." The
16 last possibility may create an inconsistency, if the preamble is treated as a claim limitation.³

17 General Atomics argues that while ordinarily a claim preamble does not limit the scope of the
18 claimed invention, the preamble in a Jepson claim is a claim limitation that helps define the scope of
19 the claimed invention. *Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997) ("When [the Jepson] form is
20 employed, the claim preamble defines not only the context of the claimed invention, but also its
21 scope."); *see also Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1029 (Fed. Cir.
22 2002) ("[T]he fact that the patentee has chosen the Jepson form of the claim evidences the intention 'to
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24 ³The parties agree that the term "substrate" means "the substance on which an enzyme acts to
25 form a product." *See* Joint Claim Construction and Prehearing Statement, Exh. A. Except with respect
26 to "reversible" or "inhibition" reactions, it is not logically possible for the analyte to be both (1) a
27 substrate for the enzyme and (4) the product of the enzymic conversion of that substrate. Put another
28 way, as "homocysteine conversion products" are the products of, not the reagents used in, the reaction,
in most cases it appears that "homocysteine conversion products" will not be substrates of the enzyme
used in the reaction. Thus, the inclusion of "substrate" may create an inconsistency with the
"improvement" portion of the patents' claims, except when "reversible" reactions are involved.

1 use the preamble to define, in part, the structural elements of his claimed invention.’ Thus, the preamble
2 is a limitation in a Jepson-type claim.”); Manual of Patent Examining Procedure § 608.01(m) (“The
3 preamble of this form of claim is considered to positively and clearly include all the elements or steps
4 recited therein as a part of the claimed combination.”). Especially given the “public notice” function
5 of a patent, it seems fairest to read any contradiction in a patent’s claims against the patent holder. *Cf.*
6 *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) (“[W]here there is
7 an equal choice between a broader and a narrower meaning of a claim . . . the notice function of the
8 claim [is] best served by adopting the narrower meaning.”). Further, the “substrate” limitation does not
9 appear in the ‘717 patent, suggesting that the language plays some role in the ‘127 patent.

10 It is true that none of the cases cited by General Atomics involved preambles that were
11 inconsistent with the improvements disclosed in a Jepson claim. *See Rowe v. Dror*, 112 F.3d 473, 479
12 (Fed. Cir. 1997) (finding that “balloon angioplasty catheter” in preamble to claim was structural
13 limitation); *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1029 (Fed. Cir. 2002)
14 (finding that preamble that described method for “providing gas assistance to a resin injection molding
15 process” did not restrict claim to “apparatuses and methods that perform complete injection molding
16 processes”). Moreover, the federal regulations only require the preamble to contain a “general
17 description” of the prior art, not the type of detailed limitations that are ordinarily found in patent
18 claims. *See* 37 C.F.R. § 1.75(e). However, where the preamble does contain specific “elements or
19 steps,” the MEPE and the case law seem to require that they be treated as limitations, along with the
20 improvements. (MPEP § 608.01(m): preamble “is considered to positively and clearly include all the
21 elements or steps recited therein as a part of the claimed combination.”)

22 Accordingly, the Court construes “said analyte” in claim 8 of the ‘127 Patent to be “an analyte
23 which is both the ‘analyte which is a substrate for said enzyme’ and the ‘non-labelled analyte’ described
24 in claim 1.” The balance of claim 8 requires that the said analyte be a said conversion product.

25 Further, the Court construes “said analyte” in claim 9 of the ‘127 Patent to be “an analyte which
26 is both the ‘analyte which is a substrate for said enzyme’ and the ‘non-labelled analyte’ described in
27 claim 1, and is a said conversion product.” The balance of claim 9 requires that the said analyte be
28 SAH.

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V. Disputed term in claim 10 of Patent '127 and claim 4 of Patent '717: "pre-treated"

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The claims at issue here state: “The method as claimed in claim 1 wherein said sample is a blood, plasma or urine sample *pre-treated* with a disulphide bond cleaving reducing agent.” (emphasis added.) Axis-Shield argues that “pre-treated” means “altered with one or more agents prior to with (sic) contacting the sample with the homocysteine converting agent.” General Atomics’ proposed construction is, “treated with a preparatory treatment prior to contacting the sample with the homocysteine converting agent. Pre-treated does not include the conversion of homocysteine in the sample by the homocysteine converting enzyme.”

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The patents teach only two methods of pretreatment. The first frees homocysteine in the sample from other proteins to which it may be bound. *See* Patent '127, 4:14-22. The second method removes naturally-occurring (endogenous) analyte molecules already present in the sample to prevent them from skewing the results. *See* Patent '127, 6:63-7:19. Pretreatment does, therefore, as Axis-Shield argues, “alter” the blood, plasma, or urine sample prior to engaging in steps (i) and (ii) of claim 1.

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United States District Court

For the Northern District of California

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1 **VI. Disputed terms in claim 23 of Patent '127 and claim 12 of Patent '717**

2 Claim 23 of Patent '127 and claim 12 of Patent '717 each state: "The kit as claimed in claim 18
3 [(claim 11 in Patent '717)] comprising in a first compartment inactive SAH-hydrolase and in a second
4 compartment a reducing agent, whereby to produce on admixture of the contents of said first and second
5 compartments activated SAH-hydrolase." These "kit" claims involve the same process described *supra*,
6 in which a reducing agent is combined with inactive SAH-hydrolase, thereby activating it. This is
7 necessary because the preferred enzyme, SAH-hydrolase, tends to become inactive during storage. *See*
8 Patent '127, 7:42-67.

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10 **A. "in a first compartment inactive SAH-hydrolase"**

11 General Atomics suggests that this term be construed to mean "the kit does not contain an active
12 SAH-hydrolase before the kit is used." However, nothing in the claims or specifications requires that
13 the inactive SAH-hydrolase be completely inactive. The Court therefore adopts Axis-Shield's proposed
14 construction, which is, "the contents of a first compartment of the kit includes inactive SAH-hydrolase."

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16 **B. "reducing agent"**

17 This term is easily construed without looking beyond the plain text of the immediate claim. The
18 reducing agent is designed "to produce . . . activated SAH-hydrolase" when combined with inactive
19 SAH-hydrolase. In the context of these "kit" claims, therefore, "reducing agent" is "a substance that
20 can restore the catalytic activity of the inactive SAH-hydrolase."

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22 **C. "activated SAH-hydrolase"**

23 The parties agree that "inactive SAH-hydrolase" is "SAH-hydrolase that is incapable of acting
24 as a catalyst." It follows that "activated SAH-hydrolase" is "SAH hydrolase that is capable of acting
25 as a catalyst." Axis-Shield's proposed construction is, "SAH hydrolase in a form that is capable of
26 catalyzing the hydrolysis of SAH and the reverse reaction." If specifying the particular reactions which
27 the SAH-hydrolase is capable of catalyzing were critical, presumably the agreed construction of
28 "inactive SAH-hydrolase" would similarly specify that the SAH-hydrolase is only incapable of acting

1 as a catalyst for those reactions. General Atomics' construction is "the inactive SAH-hydrolase that has
2 been activated by addition of a reducing agent." This construction does little to illuminate the meaning
3 of "active," and merely re-states what is obvious from plain meaning of the whole sentence: that the
4 activation occurs by combination with the reducing agent. Accordingly, the proper construction of
5 "activated SAH-hydrolase" is "SAH hydrolase that is capable of acting as a catalyst."

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CONCLUSION

8 For the foregoing reasons and for good cause appearing, the Court hereby adopts the
9 constructions set forth above.

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IT IS SO ORDERED.

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Dated: September 26, 2006

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SUSAN ILLSTON
United States District Judge

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